

REMARKS

Applicant reminds the Examiner of the new attorney docket number of 1311.DDN.CN and requests that the file be changed to reflect such change and that all future communications use this new attorney docket number.

In the office action of July 14, 2005, the Examiner rejected claims 60-67, 69-92, and 94-106 as unpatentable over Williams ('995) in view of Schlamp ('265), and claims 68 and 93 in view of Williams, Schlamp, and Liff ('485). The Examiner also rejected claims 60-67, 69-92, and 94-106 as unpatentable over Lion ('491) in view of Lion ('575).

Amendments to the claims are as follow:

Applicant has amended various of the independent claims to replace the term 'selecting' a dispenser with 'utilizing' a dispenser, as the term selecting was somewhat unclear. Other than this change, independent claim 60 has not been amended. Claim 64 has been amended to clarify the claim language. Claim 66 has been amended to recite that the counseling be provided via the dispenser. Claim 69 has been amended to recite that the dispensing machine verify the prescription with the customer after the customer enters information, and that the prescription is dispensed after verification of the prescription. Claim 75 has been amended to recite that at least two pieces of information are received into the dispenser from the customer to verify identification of the customer. (See page 12, lines 12-16). Claim 77 has been amended to clarify that the dispenser bill a third party for at least a part of the prescription. Independent claim 81 has been amended to add the word 'be' to correct a grammatical error, but otherwise remains without amendment and is not amended as to the scope or meaning of the claim. Claim 86 has been amended to add the word 'a' to correct a grammatical error. Claim 95 has been amended to recite electronically scanning the prescription to store information about the prescription in the

control portion, and to correct a grammatical error. Claim 101 has been amended to recite that dispensing the prescription involve moving the prescription from a prescription receiving structure to a dispensing structure. Claim 103 has been amended to recite sensing the prescription via sensors integral to the dispenser to verify the location of the prescription. New claims 107 through 112 have been added which are patentable over the prior art.

Applicant has reviewed the prior art patents, and respectfully submits that the prior art references do not teach the claimed elements, as will be discussed. Applicants notes that the Examiner rejected 47 claims with merely a page of discussion, and did not set forth where the prior art teaches the claim elements. Should the Examiner maintain the rejections, it is requested that he specify where in the prior art references the elements are shown in a non-final rejection so as to allow Applicant an opportunity to address the rejection.

The prior art relied upon by the examiner fails to suggest the combination of elements set forth in the claims. To the contrary, the more pertinent pharmaceutical prior art teaches away from elements of the claims. Applicant's invention is concerned with the process of delivering a filled prescription to customers. Most of the prior art references address other portions of the prescription filling process.

With respect to the combination of Lion and Lion, Lion ('575) teaches a machine and system for automatically measuring and packaging drugs. The machine holds a large number (hundreds) of various drugs, with each of the drugs contained in an individual container. Commonly used drugs are stocked into the machine. Upon entry of a prescription, the machine automatically selects the proper drug, counts the number of drug tablets, places the tablets in a bottle, seals the bottle, and labels the bottle. The machine may even form the bottles from bulk plastic materials. See Abstract, Field of the Invention, Background at column 1 lines 48-54,

Detailed Description at column 4 lines 14-19. The ‘575 patent only teaches a machine for automatically filling a prescription by forming the labeled bottle full of drugs (column 4 lines 14-19, Description in general). The ‘575 patent has no teaching about a system for delivering the prescription to customers.

Lion (‘491) teaches a method of vending prescriptions whereby the pharmacist and pharmacy are replaced completely by a vending kiosk. The kiosk will have a prescription bottling machine according to Lion ‘575, and will thus contain many containers of bulk drugs which are commonly used. A patient may go to a kiosk and enter in a prescription. If the prescription has been verified and cleared by an online (internet) pharmacist, the machine will automatically place the pills in a bottle, label the bottle, dispense the bottle to the patient, and bill the patient. Thus, Lion ‘491 teaches the elimination of the pharmacy by providing such a kiosk which automatically fills and dispenses a prescription on demand to a patient. The ‘491 patent teaches that any apparatus capable of delivering drugs without the intervention of an operator other than a customer (without a pharmacist) is in accordance with the patent (column 2 lines 50-55). Lion ‘491 thus teaches away from Applicant’s invention. Applicant teaches maintaining the pharmacy and providing a dispensing machine operated by the pharmacist, and Lion teaches complete elimination of the pharmacy.

It will thus be appreciated that the combination of the Lion references does not teach Applicant’s invention. The Lion references teach elimination of the pharmacy by replacement with a kiosk that automatically fills and dispenses prescriptions on demand (teaching away from claim elements maintaining the pharmacy and requiring storing filled prescriptions). Regarding claim 60, Lion does not teach selecting a dispenser located in a pharmacy, having a first side accessible by a pharmacy worker and a second side accessible to the public, and having

receptacles for receiving filled prescriptions, and does not teach the steps of loading a filled prescription into a dispenser, storing information about the patient, storing the filled prescription, and associating the location of the prescription with information about the patient. In fact, Lion '491 teaches a mechanism to prevent placing filled containers in a dispensing machine, as the machine fills the orders on demand. Applicant is claiming a method whereby prescriptions are filled and then loaded into a dispenser which is part of a pharmacy and stored until a patient retrieves the prescription. Because even a combination of the Lion patents does not teach each element of claim 60, claim 60 and all claims depending therefrom are allowable.

Furthermore, each of the dependent claims is patentable over the combination of the Lion patents. Claim 61 has several steps, including loading a plurality of filled prescriptions into a plurality of receptacles, that are not taught in the Lion combination. In either Lion patent, the prescriptions are apparently filled on demand, so there is no need for receptacles.

Claims 62-65 add patentability, as neither Lion suggests the combination of claim 60 combined with locating the machine in a pharmacy wall, loading from one side and dispensing from the opposite side, etc.

Applicant also submits that the Lion combination does not teach the elements of claim 60 combined with the elements of claims 66, 67 or 68.

Similarly, claim 69 is patentable over the Lion combination. The Lion combination does **not** teach the steps of selecting a dispensing machine having a plurality of receptacles for receiving filled prescriptions and loading filled prescriptions into a machine, and later dispensing the filled prescription after entering information. As discussed, the Lion combination teaches elimination of the pharmacy, and the filling and dispensing of prescriptions on demand, teaching

away from storage of filled prescriptions and other claim elements. Claims 70-74 depend from claim 69 and add additional points of novelty.

Claim 75 is patentable, as the Lion combination does not teach filling a plurality of prescriptions, selecting a medication dispenser having a plurality of receptacles for receiving filled prescriptions, loading the plurality of filled prescriptions into the receptacles, entering the location of the filled prescriptions and patient information into a control portion, correlating the location to the patient information, and verifying whether received information identifies a patient which corresponds to a prescription. The Lion combination does not teach the use of multiple pieces of information to verify the patients identity. Claims 76-80 add further steps that are patentable over the Lion combination.

Claim 81 is patentable, as the Lion combination does not teach loading a filled prescription into a dispensing system and a dispensing system disposed so as to be accessible from both sides of a pharmacy wall (particularly as Lion teaches elimination of a pharmacy) to the pharmacy and to the public. Lion teaches away from storing filled prescriptions in a pharmacy, but teaches filling on demand from a kiosk.

The dependent claims add further points of novelty. For example, nothing in the Lion combination suggests scanning information and using the scanned information to determine the location of a filled prescription as set forth in claims 82-83. To the contrary, Lion makes the prescriptions on demand, so there would be no need to track their location. Likewise, there is no teaching of using a sensor to determine if a filled prescription is in a medication holding receptacle (claim 86), as such would be completely unnecessary in the combination raised by the examiner.

Claims 87-88 are clearly patentable over the Lion combination because the Lion combination does not teach loading filled prescriptions, nor does it teach a plurality of doors adjacent the holding receptacles, or the use of holding receptacles. The Lion combination teaches against such steps and structures. Claims 89-94 add additional points of novelty.

Claim 95 is patentable as the Lion combination does not teach pharmacy personnel placing filled prescriptions into holding receptacles of the dispenser, scanning the prescription to store information about the prescription, or correlating the location of the filled prescriptions with information about the prescription. The Lion combination teaches away from such steps. The dependent claims add further points of novelty. For example, the Lion combination does not teach a method which includes disposing a dispensing system on a pharmacy wall (claim 97). The Lion combination likewise does not teach the use of a plurality of dispensing doors (claim 110).

Claim 101 is patentable as the Lion combination does not teach selecting a dispenser located in a pharmacy and accessible to the public, entering information regarding the patients into a control portion, loading filled prescriptions into a plurality of receiving structures in a dispenser, correlating the location of filled prescriptions to the identity of the patient, and confirming that a prescription for the patient is loaded into the dispenser. Rather, one Lion reference teaches automatic prescription bottling, while the other Lion reference eliminates both the conventional pharmacy and pharmacist and fills prescriptions on demand.

Claim 103 is patentable as the combination does not teach selecting a dispenser located at least partially in the pharmacy and having receiving structures for holding prescriptions, loading a filled prescription into the dispenser, and associating the location of the filled prescription with the identity of a patient. The Lion '491 patent teaches the elimination of the pharmacist

altogether, and neither Lion teaches having pharmacy staff load filled prescriptions into a plurality of prescription receiving structures. Claims 104-106 add further points of novelty.

Applicant notes that the Lion patents are directed towards an entirely different method than the present application. The Lion patents teach (1) a machine for automatically filling prescriptions, and (2) replacing a pharmacy and pharmacist with a kiosk which automatically fills prescriptions on demand. Applicant claims a process where filled prescriptions are loaded into a dispenser in a pharmacy. Applicant claims a novel dispensing method whereby previously filled prescriptions are stored in a pharmacy based dispenser until dispensed. The Lion combination simply does not teach the claim elements. Additionally, it would not be obvious to further modify the Lion combination to achieve Applicant's invention as Applicant's invention is contrary to the purposes of at least the Lion '491 invention. There is simply no support for the position that the Lion combination teaches the claimed elements, or would be modified by one of skill in the art to arrive at Applicant's invention because the Lion combination teaches such a completely different method which teaches away from the steps of Applicant's claims.

Applicant therefore submits that the claims are patentable over the Lion combination.

With regards to the rejections over the combination of Williams and Schlamp, Applicant respectfully objects to the combination and submits that neither of the references, nor their combination, disclose Applicant's invention. Additionally, Applicant submits that Schlamp would not be looked to by one of skill in the pharmacy arts and provides no motivation to modify the available pharmacy distribution systems, and that the pharmacy distribution system patents cited by the examiner teach away from combination with Schlamp and teach away from Applicant's invention.

Applicant respectfully suggests that the analysis of Schlamp and Williams is improperly based on Applicant's own disclosure. The Courts have recognized that given the "subtle but powerful attraction of a hindsight-based obviousness analysis," one must apply "rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Beasley*, 117 Fed.Appx. 739 (Fed. Cir. 2004)(quoting *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

Significant differences exist between the distribution of drugs and the distribution of conventional goods. A person of ordinary skill in the pharmaceutical arts would not look to conventional distribution of goods or conventional automation as these fields do not address special needs of the pharmaceutical arts. These differences include a need for heightened security and control, and specific requirements for labeling and handling of the drugs. Nearly all states have pharmacy boards which closely regulate the storage and distribution of drugs.

Thus, Applicant submits that one of ordinary skill in the art of the present invention is a pharmacist, pharmacy technician or other individual with experience in the distribution of prescription medications. Such a person would be familiar with the significant regulatory and safety requirements and the need to ensure that a particular container of medication is delivered to the proper person.

In conventional systems for providing goods to customers, it is typically unimportant which particular good is sold to a particular customer. It is merely important that goods are available for purchase. Additionally, goods are fungible. Each item is identical to many other items of the same model. There is thus no need to label and designate a particular item for a customer. Conventional goods are also low in risk and require low levels of security. No real danger arises where a customer accidentally purchases a DVD player instead of a VCR, or

purchases the wrong model of VCR. While the customer may be upset, the error can readily be remedied and is largely inconsequential.

Conversely, it is critical that no errors occur in the sale and distribution of drugs and medication. It is critical that a particular container of medication, packaged for a particular patient, is delivered to that patient. Substantial injury or even death can occur where a prescription drug is erroneously delivered and consumed by an incorrect patient, or where drugs are not available due to delivery problems. Because of the criticality of properly delivering medication, the process of delivering drugs is tightly regulated and requires many additional steps and precautions unimportant to conventional product distribution systems and devices. Thus, Schlamp does not disclose a system suitable for distribution of drugs as it does not address many of the required steps (as discussed below with respect to the individual independent claims). Schlamp does not provide for the specific controls set forth in the claims, because it is really unnecessary. If a customer accidentally enters the wrong account number in Schlamp, he or she may simply receive some good other than that which is desired. Thus, for example, there is no need in Schlamp to scan each item placed in a receptacle and coordinate it with patient specific information. Thus, one of skill in the pharmacy arts would not look to conventional product distribution methods, such as Schlamp, as these methods do not require or provide the high level of safety and control over distribution that is required for drugs, and do not perform the required steps for distributing drugs.

Schlamp is not suitable for the dispensing of medication as it lacks required safety and handling, and makes no teaching for the dispensing of medication or suggestion for modification to be suitable for delivery of drugs.

The pharmacy patents cited as prior art teach away from combination with Schlamp. It is important to recognize the scope of the problem being addressed by the pharmacy industry in delivering drugs. Often, patients are dissuaded from retrieving a prescription from a pharmacy because of long wait times and long lines of people at the pharmacy. Pharmacists often spend a significant portion of their time operating a cash register instead of helping patients. The existing methods of operating a pharmacy to dispense drugs are inefficient and reduce the effectiveness of the pharmacist and dissuade patients from purchasing their prescriptions.

The patents cited as prior art which deal with the problem of more efficiently delivering filled prescriptions to a patient or customer teach away from Applicant's invention, and teach away from combination with Schlamp. The patents cited which deal specifically with a pharmacy and with improved delivery of a filled prescription to a patient include Rosenblum (U.S. 6,529,801), Lion ('491), and Williams. Lion ('491), and Rosenblum teach elimination of the pharmacy and replacement with a kiosk or freestanding dispenser which contains a large number of bulk containers of commonly used medications, and which automatically fill, label, and dispense a prescription on demand. A patient requests the prescription, and the prescription is then immediately filled and delivered to the patient. Such patents teach against devices as claimed by Applicant, as they teach the effective elimination of the pharmacist and the pharmacy. These patents teach away from storing filled prescriptions.

Williams teaches that the pharmacy is improved simply by speeding up the bottling of drugs to form a filled prescription. Williams teaches maintaining the conventional pharmacy layout and functioning, with the exception of automation and computer assisted checking of the bottle filling process. (See Summary of the Invention, Detailed Description). Williams teaches a will-call area where filled prescriptions are stored. The will call area is simply a plurality of

shelves or slots to hold the prescriptions. The will-call area is located behind the pharmacy counters where customers are not allowed, and “when the customer comes to the pharmacy for pickup, the sales clerk/cashier goes to the proper holding slot of the prescription holding component and picks the prescription order.” “The cashier will accept payment and give the prescription order to the customers”. See Figure 1 and column 10 lines 48-62. The Examiner will appreciate that, based the teachings of Williams and Schlamp, it is inconsistent to combine Williams and Schlamp. Williams teaches a will call area which is off limits to the customers, and thus teaches away from an automatic dispenser as shown in Schlamp. Thus, the Examiner will appreciate that all of the prior art directly dealing with the delivery of a prescription of a filled prescription to a patient teaches away from Schlamp. The pharmaceutical prior art either teaches elimination of the pharmacy, or teaches a will-call area inaccessible by patients.

Applicant has taken an altogether different approach of providing a dispenser which stores previously filled prescriptions and which allows patients to receive and pay for their prescriptions on their own, allowing after hours delivery as well as daytime convenience. Applicant’s invention leaves the pharmacist in the pharmacy and with free time to answer patient questions and be of use to the patients.

Thus, the Examiner will appreciate that the prior art patents related to pharmacy distribution of medication provide no motivation to use a dispensing device as claimed by applicant, and where directly concerned with prescription delivery to a patient, teach away from such a device. The prior art pharmacy patents also provide no motivation for combination with Schlamp, and in most cases teach away from combination with Schlamp.

Until Applicant’s invention, the pharmacy industry did not look to machines such as in Schlamp, even though used in other industries, as a viable solution.

Applicant notes that subsequent to the filing for letters patent and public disclosure of Applicant's invention, other entities have filed for patents on virtually identical devices (Rosenblum (U.S. Patent No. 6,892,941), Pinney (U.S. Publication No. 2005/0023286)). In fact, Rosenblum (U.S. Patent No. 6,529,801) initially proposed the kiosk approach. However, after the present invention was disclosed to pharmacy boards in 2000 and 2001, Rosenblum added a new approach similar to that claimed in Applicant's invention.

Additionally, Applicant has received substantial unsolicited media coverage of the invention, and has received significant product inquiries and orders for the invention. (See Declaration of William Holmes). It should thus be appreciated that Applicant's invention represents a revolution in pharmacy technology.

As discussed above, Applicant submits that Schlamp is not relevant prior art because Schlamp contains no teaching for the distribution of drugs, and because the pharmacy patents contain no teaching for combination with the Schlamp device and teach away from combination from the Schlamp device. Applicant further submits that the pharmacy patents teach away from Applicant's invention, as they teach modifying the pharmacy distribution of drugs in two methods completely different from Applicant's invention.

In the alternative, Applicant also submits that the combination of Schlamp with the pharmacy patents does not teach all the elements of Applicant's invention. Claim 60 is patentable over the combination as it shows using an automated dispenser located in a pharmacy, storing information about the patient in the dispenser, and associating the location of the prescription with information associated with the patient. Even a combination of Schlamp and Williams does not teach each of these elements.

Likewise, Schlamp does not include the step of storing patient information and dispensing the product in conjunction with receipt of verifying information. Schlamp merely requires the input of a customer account number or customer identification number. (See Col. 6, lines 33-44). If Schlamp were used to dispense medications, individuals who are not authorized to obtain certain medications could do so simply by entering numbers until one matched a number of a customer with a prescription in the machine.

With respect to claim 66, Schlamp clearly does not teach providing patient counseling regarding the prescription via the automated dispenser.

With respect to claim 68, the addition of Liff et al. does not meet the claim elements. While Liff et al. can generate forms for billing (which is different than actually billing a third party), it does not do so as part of delivering the prescription to the patient. Rather it is done by the pharmacist or other health care worker. This is one of the problems which is present in pharmacies today. Insurance companies and the government are often billed when prescription is prepared. A fair number of prescriptions, however, are not picked-up by customers immediately. If the prescription is not retrieved within a certain amount of time, the pharmacy has to reverse the charges to the insurance company or face certain sanctions. Applicant's invention resolves this problem by billing the patient upon distribution, not upon preparation of the prescription. Thus, the pharmacy need not reverse charges – thereby further reducing the work load of pharmacy staff.

Claim 69 is patentable over the combination as it recite loading a filled prescription into the dispenser, entering the location of the prescription into the dispenser, entering patient information and prescription information into the dispenser, and dispensing the prescription after a customer has entered sufficient information to identify the patient. The claim further requires

the automated dispenser verifying the prescription with the customer after entering customer information and before dispensing the prescription. Schlamp clearly does not teach such a step. These elements are not taught in the prior art. The remaining dependent claims add additional points of novelty.

Claim 75 is patentable over the combination as it recites entering patient information and the location of the prescriptions into the dispenser, and correlating the location of the prescriptions to the patient information, which are not taught by the prior art. The claim further recites receiving at least two pieces of patient information to confirm the identity of the patient. Schlamp merely provides access to a container, and there is no system for ensuring the proper loading and presence of the proper product in the container. The dependent claims add further points of novelty not taught in a combination of Schlamp and Williams.

Claim 81 is patentable over the combination as it recites loading the prescription into a dispenser disposed in a pharmacy wall such that one side is accessible to pharmacy workers for loading the dispenser and one side being accessible to the public for dispensing prescriptions. This is not taught in the prior art.

Claims 82-83 is patentable as Schlamp does not teach scanning information about a filled prescription and storing that information in a control unit, nor does it teach using the scanned information to determine the location of the filled prescription.

Likewise, claims 84-86 are patentable, as Schlamp does not teach correlating customer information to ensure that the customer is authorized to receive a particular prescription, coordinating patient information and a receptacle, and using a sensor to ensure that the prescription is in a receptacle. Claims 87-90 add additional points of novelty.

Claim 91 is allowable, as Schlamp fails to teach dispensing the medication through a trough as set forth in the claim.

Claim 93 is allowable, as the combination of prior art fails to teach charging a third party one the medication has been dispensed.

Claim 94 is allowable as the prior art does not teach periodically removing undispensed prescriptions.

Claim 95 is patentable over the combination as it recites pharmacy personnel loading the prescription into a dispenser located in a pharmacy, electronically scanning the prescription to store information about the prescription in the control portion of the dispenser, and dispensing the prescription after input of information sufficient to verify authorization to pick up the prescription. This combination of elements is not taught in the prior art. Claims 96-100 add further points of novelty over the prior art.

Claim 101 is patentable over the combination as it recites selecting a dispenser located in a pharmacy, entering information regarding a plurality of patients into the dispenser, loading a plurality of prescriptions into the dispenser, and confirming that a prescription for a patient is loaded into the dispenser, not taught by the prior art. For example, Schlamp does not teach entering information regarding a plurality of patients and correlated prescription information, and then using that information to obtain access to the prescription. Schlamp makes no provision to verify that any object is loaded into the dispenser. Schlamp also does not teach moving the prescription from a receiving structure to a separate dispensing structure as claimed. Dependent claim 102 is also allowable.

Claim 103 is patentable over the combination as it recites loading the prescription into a pharmacy based dispenser, and associating the location of the prescription with the identity of

the patient. These elements are not taught in the prior art. Claim 103 further recites sensing the prescription via sensors integral to the automated dispenser to verify the location of the prescription, clearly not taught by the prior art, including Schlamp.

The Examiner previously maintained that it would be obvious to modify Williams and Schlamp to accomplish Applicant's invention. However, no motivation or suggestion is found in the prior art to make such a modification. In fact, the prior art, as discussed above, teaches away from Applicant's invention.

New independent claim 107 is allowable over the prior art, including Schlamp, as it recites loading prescriptions into a pharmacy based dispenser, sensing the prescription with an electronic sensor to verify the location of the prescription, requiring a customer to enter multiple pieces of information to confirm the identity of the patient and/or prescription, the dispenser verifying the prescription with the customer, and dispensing the prescription after verification. These elements are clearly not taught in the prior art, including Schlamp.

Claim 108 recites that a sensor integral to the dispenser sense the prescription to verify location. Claim 109 recites moving the prescription from the receiving structure to a separate dispensing structure to dispense the prescription. Claim 110 recites scanning the prescription before or during loading to enter information about the prescription into the dispenser control portion. Claim 111 recites sensing the prescription with an electronic sensor to determine if a filled prescription is in a receiving structure. Claim 112 recites the dispenser automatically billing a third party. All of these claim elements are not taught in the prior art, including Schlamp.

Applicant has thus demonstrated that the cited pharmaceutical art teaches away from combination with Schlamp, and teaches away from Applicant's invention. Applicant has also

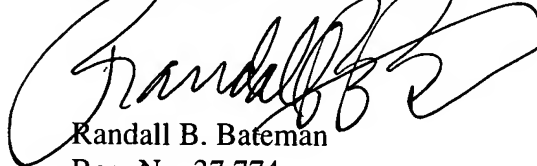
shown that the prior art clearly fails to teach the elements of Applicant's claims. Applicant therefore requests that the Examiner allow the pending claims.

Applicant has included a credit card authorization in the amount of \$475.00: \$225.00 to cover the extension fee for response within the second month and \$250.00 to cover the excess claim fee.

Applicant requests that the Examiner contact Randall B. Bateman at (801) at 533-0320 to discuss any concerns with the above amendment or the now pending claims. The Commissioner is hereby authorized to credit any overpayment and debit any amount owing to Deposit Account No. 50-2720.

Sincerely,

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